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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09 759,708	01 12 2001	Gary E. Henke	P04840US0 PHI 1316	2745

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EXAMINER

MEHTA, ASHWIN D

ART UNIT PAPER NUMBER

1638

DATE MAILED: 12 26 2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/759,708

Applicant(s)

HENKE, GARY E.

Examiner

Ashwin Mehta

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 21 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The rejection of claims 1-32 under the judicially created doctrine of obviousness-type double patenting is withdrawn in light of the claim amendments.
3. The rejection of claims 1-32 under 35 U.S.C. 102(e)/103(a) is withdrawn in light of the claim amendments.

### ***Specification***

4. The specification is objected to for containing blank lines on page 7 in the last paragraph.

### ***Claim Objections***

5. Claims 12, 16, 25, and 29 remain objected to, for the reasons of record stated in the Office action mailed 19 June 2002 under item 1. Applicant traverses the objection in the paper filed 21 October 2002. Applicant argues that the claims have been amended by replacing "A" with --The-- (response, page 8, 4<sup>th</sup> paragraph). However, the claims have not been amended.

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*Claim Rejections - 35 USC § 112*

6. Claims 1-32 remain and new claims 33-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record stated in the Office action mailed 19 June 2002 under item 3. Applicant traverses the rejection in the paper received 21 October 2002. Applicant's arguments were fully considered but were not found full persuasive.

Regarding the indefinite issue of the recitation "X1139Y" and "X1139Y (commercial designation \_\_\_\_)": Applicants provide assurance that seed of corn plant X21139Y will be deposited with the ATCC, and the deposit number inserted into the claims, upon receipt of a notice of allowable claims (response, page 9, last paragraph). This assurance satisfies the issue concerning the recitation "X1139Y." However, the rejection is applied to new claim 33, as it refers to two other corn plants, GE565937 and GE502199. No assurances have been provided concerning their ATCC deposit. Applicants also argue that the recitation "(commercial designation \_\_\_\_)" has been removed from the claims 11, 15, 19, 24, 28, and 32 (response, page 10, first paragraph). However, the recitation still appears in claims 1, 5, and 7.

Regarding the indefinite issue concerning the relative terms in claims 11, 15, 19, 24, 28, and 32: Applicant argues that each of the claims recites two requirements: that X1139Y be an ancestor of the plant, and that the claimed plant be "capable of expressing a combination of at least two X1139Y traits" selected from a Markush grouping (response, page 10, 3<sup>rd</sup> paragraph). However, this issue was not raised in this rejection. Applicant also argues that the terminology of the adjectives is well known in the art and would be understood by one skilled in the art.

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Applicants also argue that it is against the policy of the patent statutes to bar patent protection for inventions that are incapable of precise definition and assert that the terms in the claims are as precise as the subject matter of the invention permits (response, paragraph bridging pages 10-11 to page 11, 1<sup>st</sup> full paragraph). However, it remains unclear how one would differentiate, for example, "excellent" yield potential from "good" or "very good" yield potential. It is not clear if a plant that has good yield potential and above average root strength, for example, would be encompassed by the claims.

In claim 6: there is improper antecedent basis for "protoplasts" in line 1. It is suggested that the term be removed from the claim, and that a new claim be introduced directed towards protoplasts produced from the tissue culture of claim 5.

In claims 8 and 21: the recitation "has been manipulated to be male sterile" renders the claims indefinite. It is not clear if the claim is directed towards detasseled plants, or plants that have been transformed with a gene conferring male sterility. The following amendments are suggested: 1) in claims 8 and 21, replace "manipulated to be male sterile" with --detasseled--; 2) add a new claim 42 directed towards a method of producing a male sterile maize plant comprising transforming the maize plant of claim 2 or 20 with a transgene that confers male sterility, and a new claim 43 directed towards a transgenic male-sterile maize plant produced by the method of claim 42.

In claim 33: the recitation "developing from the cross a hybrid maize plant" in line 4 renders the claim indefinite. The claim does not clearly indicate that the hybrid maize plant in the recitation is the same as X1139Y, mentioned in line 1. It is suggested that in line 4, "a" be replaced with --said--.

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In claim 34: the recitation "essentially" in line 3 renders the claim indefinite. The recitation makes the metes and bounds of the claim unclear.

In claim 39: the recitation "on average, at least 50%" in line 2 renders the claim indefinite. It is not clear what is being referred to by this recitation. The metes and bounds of the claim are not clear.

In claim 40: the recitation "A X1139Y maize plant selected from the population of X1139Y progeny maize plants" renders the claim indefinite. The claim is drawn to plant X1139Y, yet can comprise less than 100% of the alleles of X1139Y.

In claim 41: the recitation "further comprising applying double haploid methods" renders the claim indefinite. The recitation broadens the scope of parent claim 38, which only involves crosses and does not encompass any double haploid method. It is also not clear what double haploid method is being referred to.

In claims 11, 15, 19, 24, 28, 32, 39, and 40: the recitations "has derived at least 50% of its ancestral alleles" in claims 11, 15, 19, 24, 28, and 32, and "deriving at least 50% of its ancestral alleles" in claims 39 and 40 render the claims indefinite. It is not clear what is meant by "derived" and "deriving." Have the alleles been transformed into the claimed plants, did the claimed plants inherit the alleles in crosses, etc.? It is suggested that "derived" and "deriving" be replaced with --inherited-- and --inheriting--.

7. Claims 11-19, and 24-32 remain and claims 9, 10, 22, 23, 34-41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the

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inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed 19 June 2002 under item 4. Applicants traverse the rejection in the paper received 21 October 2002. Applicants' arguments have been fully considered but were not found fully persuasive.

Applicants argue that the claim amendments overcome the rejection for claims 8 and 21 (response, page 12, 4<sup>th</sup> paragraph). The amendments overcome the written description issue raised for these claims, and the rejection is withdrawn from claims 8 and 21.

Applicants argue that the claims have been amended by adding the threshold, having 50% of the ancestral alleles, that limits the variation permitted among the genus, as well as an assayable function, capable of expressing a combination of at least two traits of X1139Y. Applicants argue that in plants, identifying characteristics are those detectable in the phenotype, which is manifested through gene expression, and that claims to a particular species of invention are adequately described if the disclosure of relevant identifying characteristics is present in the application. Applicants argue that one of ordinary skill is reasonably apprised in knowing that a plant crossed with X1139Y will result in a plant having half the genetic contribution of X1139Y, and that a further limitation set is that the plants must be capable of expressing a combination of at least two phenotypic characteristics of X1139Y (response, page 13, 1<sup>st</sup> and 2<sup>nd</sup> paragraphs). However, the specification does not provide a description of the alleles of X1139Y, nor does it describe the functions that are associated with each of the alleles of X1139Y. The specification does not describe the alleles that govern the expression of any of the traits enumerated in the claims. As the alleles of X1139Y are not described, neither are the alleles of its descendents.

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Further, the new claims encompass plants that can express any traits, none of which are described.

Applicant also argues that the specification supplies an extensive definition and description of "transgene" and transgenes of interest. Applicant argues that the trivial modification introduced by the transgenes to X1139Y are clearly supported and described in the present application (response, paragraph bridging pages 13-14). However, as written, the claims encompass any and all transgenes, even those that have yet to be isolated and for which descriptions are unknown. Further, the effect that a transgene can have on its host plant depends on the function of its encoded product, among other considerations, and the modification cannot simply be described as "trivial." A transgene that is a transcription factor, for example, could effect the expression of numerous genes and phenotypes. It is suggested that claims 12 and 25 be amended by listing the types of transgenes that may be introduced, provided that the specification or the prior art indicates that the gene has been isolated, for example genes that confer resistance to a plant virus

Applicant also argues, regarding the description of plants produced by the methods involving breeding programs, that pedigree association with physical appearance or performance in plants allow parents that have contributed favorable alleles for desirable traits through selective breeding programs to be identified, and that performing the breeding steps described in the specification will provide plants which retain the beneficial features of X1139Y and the transgene (response, paragraph bridging pages 14-15). However, descriptions of all of the traits of the plants produced by the breeding programs are not provided.



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Further, the specification does not describe any traits of any inbred plants or any progeny plants produced from X1139Y, nor does it mention any double haploid method. While plants produced by selfing or sib pollinating X1139Y would inherit all of their alleles from X1139Y, the morphological and physiological characteristics of the progeny plants would be different from those of X1139Y, and they are not described.

8. Claim 33 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record stated in the Office action mailed 19 June 2002 under item 5 for claims 1-32. Applicant traverses the rejection in the paper filed 21 October 2002. Applicant's arguments have been fully considered and found persuasive for claims 1-32. However, Applicant's arguments were not persuasive for new claim 33.

The claim is drawn towards a method of making a hybrid plant designated X1139Y comprising crossing inbred maize plants GE565937 and GE502199.

Applicant has provided assurance that the seed of hybrid X1139Y will be deposited with the ATCC, and that the application will be amended to recite the assigned ATCC accession number, upon receipt of a notice of allowance (response, page 15, last paragraph). The rejection is withdrawn from claims 1-32 in light of this assurance and in accordance with MPEP 2411.02.

However, lines GE565937 and GE502199 are essential to the practice of claim 33. These two lines do not appear to be readily available to the public, as they are proprietary lines, and their deposit is required.

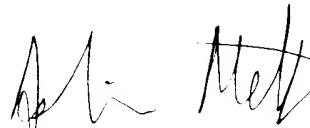
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9. Claims 1-32 remain and claims 33-41 are rejected.

***Contact Information***

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

December 22, 2002

  
ASHWIN D. MEHTA, PH.D  
PATENT EXAMINER